

ATTORNEY DOCKET NO. 14028.0292
Application No. 09/383,695

Remarks

Claims 1-10, 22, and 26-29 are pending in this application. Claims 5, 7, and 8 are withdrawn from consideration as drawn to non-elected species. Thus, claims 1-4, 6, 9-10, 22 and 26-29 are under consideration. A copy of all of the pending claims under examination and withdrawn claims is attached to this Amendment as an Appendix A because applicants are aware that the official PTO file is lost. This copy of all pending and withdrawn claims is provided only as a convenience and is not intended to be an amendment of the claims pursuant to 37 C.F.R. § 1.121(c)(3).

CLAIM TO PRIORITY

Applicants amend the specification herein by amending the claim to priority. Applicants believe this addresses the Examiner's objection to the form of the claim to priority.

The Examiner previously rejected Applicants' claims to priority that predate April 15, 1997. In particular, the Examiner alleged that support is lacking in the provisional application U.S.S.N. 60/015,459, filed April 15, 1996. In the interview with Examiners Susan Ungar and Anthony Caputa on April 3, 2003 and in responses to Office Actions dated March 12, 2002 and December 20, 2001, Applicants directed the Examiner to at least page 4, lines 15-28 (which specifically refers to methods of inducing immune tolerance and inhibiting a rejection response comprising exposing the recipient to an immunotoxin that reduces T-cell lymphocytes by 80%); page 6, lines 11-20; and page 17, lines 6-10 (which specifically refers to the sFv-DT390 immunotoxin); page 16, line 21 through page 17, line 10 (which specifically refers to method using immunotoxins comprising an anti-CD3 antibody linked to a diphtheria toxin moiety); page 12, lines 14-17 (which specifically teaches the diphtheria toxin moiety can be DT390); page 12, lines 20-22 (which teaches the antibody moiety can be scUCHT1 (sFv is the scUCHT1 antibody); page 67, lines 28-31) or other anti-CD3 antibody); page 34, lines 7-18 (which teaches a reduction of T-cells to less than or equal to 200 cells/mm³, an 80% reduction; and page 49, line 9, through page 50, line 7 (which teaches how to make the sFv-DT390 construct). Applicants note that in view of the arguments presented to the Examiner, the Examiner agreed to withdraw

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previous objections to the priority claim to U.S.S.N. 60/015,459, filed on April 15, 1996. Therefore, applicants are at least entitled to a priority date of April 15, 1996.

Additionally, the Examiner has objected to Applicants' claim to priority to the provisional application U.S.S.N. 08/739,703, filed on October 29, 1996 (the '703) and U.S.S.N. 60/008/104 (the '104 application), filed on October 30, 1995. In an effort to facilitate timely prosecution of this matter, applicants provide herein a declaration under 37 C.F.R. § 1.132 to overcome the double patenting rejection. The priority claims to the '703 and '104 applications rendered unnecessary.

DOUBLE PATENTING

The Office Action dated October 21, 2002 rejected claims 1-4, 6, 9-10, and 22 under the judicially created doctrine of obviousness type double patenting as allegedly being unpatentable over claims 1 and 3-8 of U.S. Patent No. 6,103,235 (the '235 patent) in view of Thompson et al. (JBC, 270:28037-41 (1995)).

This double patenting rejection, is overcome. As discussed above, the application is entitled to the priority claim to U.S. Patent No. 6,103,235, filed April 15, 1996 (the '235 patent). As this application claims priority through the patent at issue and therefore, both the present application and the '235 patent have the same effective filing date, the rejection is moot. Applicants respectfully request the rejection be withdrawn.

35 U.S.C. § 103

Claims 1-4 are rejected under 35 U.S.C. § 103 as allegedly obvious based on Thompson et al., JBC 270:28037-41 (1995). in view of U.S. Patent No. 5,725,857; claims 1-4, 6, 9-10, and 22 and new claims 26-29 are rejected under 35 U.S.C. § 103 as allegedly obvious based on the same references and further in view of Lu et al. (J. Amer. Soc. Nephrol. 4:1239-1256). Applicants submit herewith a declaration under 37 C.F.R. § 1.132 (Appendix B) which indicates that the Thompson reference is the applicants own work and therefore can not be used as a 35

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U.S.C. § 102(a) prior art reference in a 35 U.S.C. § 103 rejection. Applicants believe this rejection to be overcome and respectfully request its withdrawal.

35 U.S.C. § 132

The Examiner objected to the amendment of the priority claim as it incorporated by reference priority applications. The priority claim has been amended herein. Applicants believe this amendment overcomes the objection. Reconsideration and withdrawal is requested.

U.S.C. § 112, first paragraph

Claims 26-29 are rejected under 35 U.S.C. § 112, ¶ 1, for allegedly lacking enablement such that a person skilled in the art can practice the invention. In particular, the Examiner has rejected claims 26-29 for allegedly failing to teach one skilled in the art how to inhibit a rejection response in a primate recipient, by inducing immune tolerance. Applicants gratefully note that, in view of the disclosure in the specification and arguments of record made by the applicants, the Examiner has agreed to withdraw this rejection. Specifically the application teaches each and every element of the claims in such a way that one of skill in the art could practice the invention.

Applicants remind the Examiner that upon allowance of generic claims 1 and 6, applicants are entitled under 37 C.F.R. § 1.141(a), to consideration of withdrawn claims 5, 7, and 8, which are drawn to a non-elected species.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

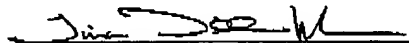
Payment in the amount of \$930.00 for Request for Three Month Extension of Time is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. It is believed that no additional fee is required

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with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any additional amount or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.


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CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence and any items indicated as attached or included are being transmitted via facsimile transmission to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Attention: Examiner Susan Ungar, Art Unit 1642, (703) 746-3142, on the date indicated below.


Tina Williams McKeon

April 11, 2003
Date